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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,197	03/27/2001	Satomi Nishikawa	P278064	3685

22242 7590 03/24/2004

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/806,197

Applicant(s)

NISHIKAWA ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 2, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-10, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 1-14 are pending in the case. Claims 2, 11 and 12 are withdrawn.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/20/04 has been entered.

#### ***Election/Restrictions***

Claims 2, 11 and 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed 9/13/02.

This application contains claims 2, 11 and 12 drawn to an invention nonelected with traverse in the paper submitted 9/13/02. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Objections***

Claims 4 and 7-9 are objected to because of the following informalities: Claims 4 and 7-9 each recited non-elected subject matter, since they depend on non-elected claim 2. This objection was originally made in the Office action mailed 12/03/02. Appropriate correction is required.

Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiply dependent claim. See MPEP § 608.01(n). Accordingly, the claims 8 and 9 have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 112***

Claims 1, 3-7, 10, 13 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 8/26/03.

To recapitulate, the written description requirement is established by 35 USC 112, first paragraph which states that the "specification shall contain a written description of the invention. . ." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, (the inventor) was in possession of the invention." See *Vas Cath B. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood e. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961 , 1966 (Fed. Cir. 1997).

This rejection is based on the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description Requirement" published in the Federal Register (Volume 66, Number 4, Pages 1099-1111).

Claim 1 as currently amended is drawn to a promoter comprising DNA (b), which is a DNA that comprises a nucleotide sequence in which one or more bases are deleted, substituted, or added in the nucleotide sequence shown in SEQ ID No. 1 and which has more than 90% identity to the nucleotide sequence of any region consisting of 250 bp or more within the nucleotide sequence of SEQ ID No. 1, and which contains

the nucleotide sequence shown in SEQ ID NO: 24. This is a genus claim in terms of any fragment which has more than 90% identical to any region of at least 250 bp of SEQ ID No. 1. The specification mentions SEQ ID No. 1. This disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all promoters comprising DNA (b) based on the teachings in the specification. The specification does not teach any 250 bp fragment of SEQ ID No. 1 which functions as a promoter. There is no correlation between sequence (structure) and the promoter function provided at all to indicate which 250 bp fragments would have promoter activity. There is no correlation to indicate a 250 bp fragment, which 10% of positions could be altered and yet maintain promoter function. Therefore, the specification does not describe the claimed promoters comprising DNA (b) in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these promoters at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Applicants have argued in their remarks submitted 2/20/04 that they have disclosed several sequences (SEQ ID NOs 3, 4, 5, and 7) which differ from the DNA in claim 1(a), which is SEQ ID NO:1. At pages 8-9 of the remarks applicants set forth the differences. However, the fact that the specification discloses several alterations in the approximately 2000 base pair polynucleotide of SEQ ID NO: 1 does not remedy the lack of an adequate written description of the invention as set forth in claim 1 (b), since all of the altered sequences contain a small substitution located in the same small region of SEQ ID NO:1, in addition to four other small deletions or insertions, and therefore are

insufficiently representative of the encompassed subject matter, which comprises any deletion, substitution or insertion of any nucleotides at any location in the 2000 base pair polynucleotide of SEQ ID NO:1. Furthermore, applicants argue that SEQ ID NO: 24 is contained within SEQ ID NO: 1 and 7, as set forth by applicants at page 9 of the remarks. While this is acknowledged, it is maintained that by virtue of the recitation of "which has more than 90% identity to the nucleotide sequence of any region consisting of 250 bp or more within the nucleotide sequence shown in SEQ ID NO:1", the claim encompasses subject matter which was not adequately described by the specification.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 13 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a promoter which may exist in nature, untouched by the hand of man. The addition of the term "isolated" would overcome this rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-7, 10, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Torikai et al. (US Patent 5,959,176).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained essentially for the reasons made of record in the previous Office actions, mailed 8/26/03 and 12/3/02.

Applicants have submitted an unsigned Declaration with their response of 2/20/04 from inventor Satomi Torikai. The rejection is maintained in the absence of a signed Declaration.

**Conclusion**


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ntv  
3/17/04

  
TERRY MCKELVEY  
PRIMARY EXAMINER